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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,565	09/29/2004	Masayoshi Takeda	Q83865	1030

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2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
GARVEY, TARA L	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,565	TAKEDA ET AL.	
	Examiner	Art Unit	
	Tara L. Garvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8,9,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☒ Claim(s) *8,9,11 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/24/04, 11/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5, 8, 9, 11 and 12 are pending. Receipt is acknowledged of an amendment filed on May 13, 2005 in which claims 1-4 were amended, claims 6, 7 and 10 were canceled and new claim 12 was added.

Priority

Please amend the specification to add a first paragraph to that indicates that this application is a 371 of PCT/JP03/07807 filed on June 19, 2003, which claims benefit of JAPAN 2002/180543 filed on June 20, 2002.

A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage

commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference

in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Please remove the hyperlink on page 5, line 2.

Appropriate correction is required.

Claim Objections

Claims 8, 9 and 11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 2, 4 and 5 are drawn to an isolated polynucleotide molecule having promoter activity for a polynucleotide encoding the amino acid sequence of SEQ ID NO: 2. The polynucleotide molecule comprises the polynucleotide sequence of SEQ ID NO: 17, a polynucleotide sequence of SEQ ID NO: 17 in which 1 to 10 nucleotides are substituted, deleted and/or inserted, the polynucleotide sequence consisting of nucleotides 3253 to 5023 of SEQ ID NO: 17 or a polynucleotide sequence consisting of nucleotides 3253 to 5023 of SEQ ID NO: 17 in which 1 to 10 nucleotides are substituted, deleted and/or inserted, an expression vector comprising the polynucleotide molecule and a cell transfected with the expression vector.

While the specification describes SEQ ID NO: 17, the specification does not describe every variant of SEQ ID NO: 17 or nucleotides 3253 to 5023 of SEQ ID NO: 17 with 1 to 10 nucleotides substituted, deleted and/or inserted that is able to maintain promoter activity. The specification merely describes SEQ ID NO: 17 or nucleotides 3253 to 5023 of SEQ ID NO: 17 and that these sequences have promoter activity. The recitation of SEQ ID NO: 17 is not representative of this broad genus of variants of SEQ ID NO: 17 or nucleotides 3253 to 5023 of SEQ ID NO: 17.

The prior art does not appear to offset the deficiencies in the specification in that it does not describe all the variants of SEQ ID NO: 17 or nucleotides 3253 to 5023 of

SEQ ID NO: 17 with 1 to 10 nucleotides substituted, deleted and/or inserted that function as a promoter for the amino acid sequence of SEQ ID NO: 2.

Therefore, there is no structural and functional basis provided by the prior art or the instant specification for one of skill in the art to envision the broad genus of variants of SEQ ID NO: 17 that maintain ability to function as a promoter. A single full-length nucleic acid sequence of SEQ ID NO: 17 is not representative of the functionally different or equivalent nucleic acids from this broad class. One of skill in the art would not have been able to envision a representative number of variations in the nucleic acid sequence of SEQ ID NO: 17 that function as a promoter for the amino acid sequence of SEQ ID NO: 2. One of skill in the art would have thus reasonably concluded that the applicants were not in possession of the claimed invention for claims 1, 2, 4 and 5.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of

isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only a nucleic acid sequence as described in SEQ ID NO: 17 or nucleotides 3253 to 5023 of SEQ ID NO: 17, but not the full breadth of the claims, meets the written description provision of 35 USC 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "said polynucleotide" is unclear. Does this refer to "an isolated polynucleotide having promoter activity" in line 1 or to "a polynucleotide encoding an amino acid" in line 2?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by DOE Joint Genome Institute and Stanford Human Genome Center (Homo sapiens chromosome 5 clone CTC-485121, complete sequence; GenBank Accession Number AC010269, August 23, 2001; cited in the IDS submitted on September 29, 2004).

Claims 1-3 are drawn to an isolated polynucleotide molecule having promoter activity for a polynucleotide encoding the amino acid sequence of SEQ ID NO: 2. The polynucleotide molecule comprises the polynucleotide sequence of SEQ ID NO: 17, a polynucleotide sequence of SEQ ID NO: 17 in which 1 to 10 nucleotides are substituted, deleted and/or inserted, the polynucleotide sequence consisting of nucleotides 3253 to 5023 of SEQ ID NO: 17 or a polynucleotide sequence consisting of nucleotides 3253 to 5023 of SEQ ID NO: 17 in which 1 to 10 nucleotides are substituted, deleted and/or inserted.

DOE Joint Genome Institute and Stanford Human Genome Center teaches a nucleotide sequence that comprises SEQ ID NO: 17 with 100% identity (see SCORE result 1 of GenEMBL). Since the reference teaches the claimed sequence, the sequence inherently has promoter activity for the polynucleotide encoding the amino

acid sequence of SEQ ID NO: 2. Thus, DOE Joint Genome Institute and Stanford Human Genome Center teaches all that is recited in the instant claims.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by DOE Joint Genome Institute and Stanford Human Genome Center (Homo sapiens chromosome 5 clone CTD-2297D10, complete sequence; GenBank Accession Number AC022424, October 3, 2001; cited in the IDS submitted on September 29, 2004).

Claims 1 and 2 have been described previously.

DOE Joint Genome Institute and Stanford Human Genome Center teaches a nucleotide sequence that comprises sequence with 99.5% identity to SEQ ID NO: 17 (see SCORE result 2 of GenEMBL). The sequence contains 6 mismatches, which reads on a polynucleotide sequence of SEQ ID NO: 17 in which 1 to 10 nucleotides are substituted, deleted and/or inserted. Since the reference teaches the claimed sequence, the sequence inherently has promoter activity for the polynucleotide encoding the amino acid sequence of SEQ ID NO: 2. Thus, DOE Joint Genome Institute and Stanford Human Genome Center teaches all that is recited in the instant claims.

Allowable Subject Material

Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a

complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey, Ph.D.
Examiner
Art Unit 1636

TLG

CELINE QIAN, PH.D.
PRIMARY EXAMINER